

SEP 14 2011

SECTION 6
510(k) SUMMARY

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4359
Fax: 508-683-5939

Contact: Ashley Pyle
Regulatory Affairs Manager
Date Prepared: July 29, 2011

2. Proposed Device:

Trade Name: Expect™ Endoscopic Aspiration Needle
Classification Name: Endoscope and Accessories & Endoscopic Ultrasound System
Regulation Number: 876.1500 & 876.1075
Product Code: FCG and ODG
Classification: Class II

3. Predicate Device:

Trade Name: Expect™ Endoscopic Aspiration Needle
Manufacturer and Clearance Number: Boston Scientific Corp, K110030 & K100712
Classification Name: Endoscope and Accessories & Endoscopic Ultrasound System
Regulation Number: 876.1500 & 876.1075
Product Code: FCG and ODG
Classification: Class II

4. Device Description:

The Expect™ Endoscopic Ultrasound Aspiration Needle (EUS-FNA) is an endoscopic ultrasound aspiration needle that can be coupled to the biopsy channel of a Curvilinear Array (CLA) Echoendoscope with a standard luer connection and delivered into the digestive tract. The needle is used to acquire aspiration samples from lesions within and adjacent to the digestive system's major lumens that can be identified and targeted using the echoendoscope. An aspiration sample is obtained by penetrating the lesion with the needle while applying suction.

5. Indications for Use:

The Expect™ EUS-FNA device is intended for sampling targeted submucosal and extramural gastrointestinal lesions through the accessory channel of a curvilinear echoendoscope.

6. Technological Characteristics:

The proposed Expect™ EUS-FNA device is a new configuration, which has a needle composed of nitinol. The currently cleared Expect™ EUS-FNA needle is composed of chromium cobalt material (K110030).

7. Performance Data:

Bench Testing has been performed on the proposed Expect™ EUS-FNA device with nitinol needle component, which demonstrates that the nitinol needle component met the required specifications for the completed design verification and biocompatibility tests.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed Expect™ Endoscopic Aspiration Needle with the nitinol needle component is substantially equivalent to the currently cleared Expect™ EUS-FNA devices with chromium cobalt needle components (K110030).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Ashley Pyle
Regulatory Affairs Manager
Boston Scientific Corporation
100 Boston Scientific Way
MARLBOROUGH MA 01752

SEP 14 2011

Re: K112198

Trade/Device Name: Expect™ Endoscopic Aspiration Needle
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODG, FCG
Dated: August 25, 2011
Received: August 26, 2011

Dear Ms. Pyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health.

Enclosure

SECTION 5
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): To Be Determined

K112198

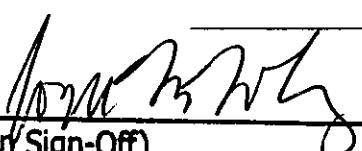
Device Name: Expect™ Endoscopic Aspiration Needle

Indications for Use: The Expect™ Needle is designed to sample targeted submucosal and extramural lesions through the accessory channel of a curvilinear echoendoscope.

Prescription Use X AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)


Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Gastro-Renal, and
Urological Devices

510(k) Number K112198

Special 510(k) Premarket Notification, Expect Endoscopic Ultrasound Aspiration Needle

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